

## STANDARD OF REVIEW

The Administrative Procedure Act (“APA”) requires this Court to “hold unlawful and set aside agency action, findings, and conclusions” that are “in excess of statutory jurisdiction, authority, or limitations”; that are made “without observance of procedure required by law”; or that are “arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.” 5 U.S.C. § 706(2)(A), (C), (D).

Claims under the APA “are adjudicated without a trial or discovery, on the basis of an existing administrative record,” and so “are properly decided on summary judgment.” *Audubon Naturalist Soc’y of Cent. Atl. States, Inc. v. DOT*, 524 F. Supp. 2d 642, 660 (D. Md. 2007). In such a case, however, the standard of review set forth in Federal Rule of Civil Procedure 56(a) “does not apply.” *Andreas-Myers v. NASA*, No. 16-cv-3410, 2017 WL 1632410, at \*5 (D. Md. Apr. 28, 2017). Instead, “summary judgment ‘serves as the mechanism for deciding, as a matter of law, whether the agency action is supported by the administrative record and is otherwise consistent with the APA standard of review.’” *Id.* (quoting *Kaiser Found. Hosps. v. Sebelius*, 828 F. Supp. 2d 193, 198 (D.D.C. 2011)). In an APA case, “the function of the district court is to determine whether or not as a matter of law the evidence in the administrative record permitted the agency to make the decision it did.” *Id.*

In assessing the legality of the challenged Guidance, this Court reviews *de novo* questions of statutory interpretation, including whether the agency acted outside the scope of its authority. *See Bowen v. Univ. of Georgetown Hosp.*, 488 U.S. 204, 208-09 (1988). The Court also “strict[ly]” reviews FDA’s compliance with the APA’s procedural requirements, relying on “its own independent judgment” without deference to the agency’s assessment of its “procedural

integrity.” *Chocolate Mfrs. Ass’n of U.S. v. Block*, 755 F.2d 1098, 1103 (4th Cir. 1985) (describing *Weyerhaeuser Co. v. Costle*, 590 F.2d 1011, 1025-28 (D.C. Cir. 1978)).

This Court’s review of whether FDA’s Guidance is arbitrary and capricious—while “narrow[er]”—nonetheless requires a “searching and careful” analysis. *Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 416 (1971). Agency action will be found arbitrary and capricious when the agency “relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem,” or “offered an explanation for its decision that runs counter to the evidence before the agency.” *Motor Vehicle Mfrs. Ass’n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983). Similarly, an agency’s failure to “cogently explain why it has exercised its discretion in a given manner” will compel vacatur. *Id.* at 48. These standards accord some deference to the agency, but this Court retains a critical role in “ensuring that [the] agenc[y] [has] engaged in reasoned decisionmaking.” *Judulang v. Holder*, 565 U.S. 42, 53 (2011); see *N.C. Wildlife Fed’n v. N.C. Dep’t of Transp.*, 677 F.3d 596, 601 (4th Cir. 2012) (“A reviewing court must ensure that the agency has ‘examine[d] the relevant data and articulate[d] a satisfactory explanation for its action,’ and must not reduce itself to a ‘rubber-stamp’ of agency action.” (citations omitted)).